



5-28-04

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Attorney's Docket No.: 16743-004001 / 12A-921112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : You-Di Liao
Serial No. : 10/813,549
Filed : March 29, 2004
Title : REMOVAL OF N-TERMINAL METHIONINE FROM PROTEINS BY
ENGINEERED METHIONINE AMINOPEPTIDASE

Art Unit : Unknown
Examiner : Unknown

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required to submit copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003, according to the July 11, 2003 waiver of the requirement.

United States Patents/Patent Publications

1. U.S. Patent No. 5,013,662

Articles

2. Abe, A., *et al.* (2000) Acetylation at the N-terminus of actin strengthens weak interaction between actin and myosin. *Biochem. Biophys. Res. Commun.*, 268:14-19.
3. Adachi, K., *et al.* (2000) Expression of functional soluble human α -globin chains of hemoglobin in bacteria. *Protein Expr. Purif.*, 20:37-44.
4. Belagaje, R.M., *et al.* (1997) Increased production of low molecular weight recombinant proteins in *Escherichia coli*. *Protein Sci.*, 6:1953-1962.
5. Ben-Bassat, A., *et al.* (1987) Processing of the initiation methionine from proteins: properties of the *Escherichia coli* methionine aminopeptidase and its gene structure. *J. Bacteriol.*, 169(2):751-757.

CERTIFICATE OF MAILING BY EXPRESS MAIL

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Date of Deposit

6. Boix, E., *et al.* (1996) Role of the N terminus in RNase A homologues: differences in catalytic activity, ribonuclease inhibitor interaction and cytotoxicity. *J. Mol. Biol.*, 257:992-1007.
7. Busby, W.H., Jr., *et al.* (1987) An enzyme(s) that converts glutaminyl-peptides into pyroglutamyl-peptides. Presence in pituitary, brain, adrenal medulla, and lymphocytes. *J. Biol. Chem.*, 262(18):8532-8536.
8. Chang, S.Y., *et al.* (1989) Methionine aminopeptidase gene of *Escherichia coli* is essential for cell growth. *J. Bacteriol.*, 171(7):4071-4072.
9. Chen, S., *et al.* (2002) The specificity *in vivo* of two distinct methionine aminopeptidases in *Saccharomyces cerevisiae*. *Arch. Biochem. Biophys.*, 398(1):87-93.
10. Chiu, C.H., *et al.* (1999) Amino acid residues involved in the functional integrity of *Escherichia coli* methionine aminopeptidase. *J. Bacteriol.* 181(15):4686-4689.
11. Endo, S., *et al.* (2001) The additional methionine residue at the N-terminus of bacterially expressed human interleukin-2 affects the interaction between the N- and C-termini. *Biochemistry*, 40:914-919.
12. Fischer, W.H., and Spiess, J. (1987) Identification of a mammalian glutaminyl cyclase converting glutaminyl into pyroglutamyl peptides. *Proc. Natl. Acad. Sci. U.S.A.*, 84:3628-3632.
13. Hirel, P.H., *et al.* (1989) Extent of N-terminal methionine excision from *Escherichia coli* proteins is governed by the side-chain length of the penultimate amino acid. *Proc. Natl. Acad. Sci. U.S.A.*, 86:8247-8251.
14. Huang, H.C., *et al.* (1998) The *Rana catesbeiana* *rcr* gene encoding a cytotoxic ribonuclease. Tissue distribution, cloning, purification, cytotoxicity, and active residues for RNase activity. *J. Biol. Chem.*, 273(11):6395-6401.
15. Hwang, D.D.W., *et al.* (1999) Co-expression of glutathione S-transferase with methionine aminopeptidase: a system of producing enriched N-terminal processed proteins in *Escherichia coli*. *Biochem. J.*, 338(Pt 2):335-342.
16. Ishitani, M., *et al.* (2000) SOS3 function in plant salt tolerance requires N-myristoylation and calcium binding. *Plant Cell*, 12:1667-1677.
17. Leu, Y.J., *et al.* (2003) Residues involved in the catalysis, base specificity, and cytotoxicity of ribonuclease from *Rana catesbeiana* based upon mutagenesis and X-ray crystallography. *J. Biol. Chem.*, 278(9):7300-7309.

18. Li, X., and Chang, Y.H. (1995) Amino-terminal protein processing in *Saccharomyces cerevisiae* is an essential function that requires two distinct methionine aminopeptidases. *Proc. Natl. Acad. Sci. U.S.A.*, 92:12357-12361.
19. Liao, Y.D., and Wang, J.J. (1994). Yolk granules are the major compartment for bullfrog (*Rana catesbeiana*) oocyte-specific ribonuclease. *Eur J Biochem.*, 222:215-220.
20. Liao, Y.D., *et al.* (2000) Purification and cloning of cytotoxic ribonucleases from *Rana catesbeiana* (bullfrog). *Nucleic Acids Res.*, 28(21):4097-4104.
21. Liao, Y.D., *et al.* (2003) The structural integrity exerted by N-terminal pyroglutamate is crucial for the cytotoxicity of frog ribonuclease from *Rana pipiens*. *Nucleic Acids Res.*, 31(18):5247-5255.
22. Lowther, W.T., *et al.* (1999) *Escherichia coli* methionine aminopeptidase: implications of crystallographic analyses of the native, mutant, and inhibited enzymes for the mechanism of catalysis. *Biochemistry*, 38:7678-7688.
23. Lowther, W.T., and Matthews, B.W. (2000) Structure and function of the methionine aminopeptidases. *Biochim. Biophys. Acta.*, 1477:157-167.
24. Moerschell, R.P., *et al.* (1990) The specificities of yeast methionine aminopeptidase and acetylation of amino-terminal methionine *in vivo*. Processing of altered iso-1-cytochromes *c* created by oligonucleotide transformation. *J. Biol. Chem.*, 265(32):19638-19643.
25. Notomista, E., *et al.* (1999) Effective expression and purification of recombinant onconase, an antitumor protein. *FEBS Lett.*, 463:211-215.
26. Prchal, J.T., *et al.* (1986) Hemoglobin Long Island is caused by a single mutation (adenine to cytosine) resulting in a failure to cleave amino-terminal methionine. *Proc. Natl. Acad. Sci. U.S.A.*, 83:24-27.
27. Roderick, S.L., and Matthews, B.W. (1993) Structure of the cobalt-dependent methionine aminopeptidase from *Escherichia coli*: a new type of proteolytic enzyme. *Biochemistry*, 32:3907-3912.
28. Shapiro, R., *et al.* (1988) Expression of Met-(-1) angiogenin in *Escherichia coli*: conversion to the authentic <Glu-1 protein. *Anal. Biochem.*, 175:450-461.
29. Tahirov, T.H., *et al.* (1998) Crystal structure of methionine aminopeptidase from hyperthermophile, *Pyrococcus furiosus*. *J. Mol. Biol.*, 284:101-124.
30. Tobias, J.W., *et al.* (1991) The N-end rule in bacteria. *Science*, 254:1374-1377.

31. Varshavsky, A. (1996) The N-end rule: functions, mysteries, uses. Proc. Natl. Acad. Sci. U.S.A., 93:12142-12149.
32. Vetro, J.A., and Chang, Y.H. (2002) Yeast methionine aminopeptidase type 1 is ribosome-associated and requires its N-terminal zinc finger domain for normal function *in vivo*. J. Cell. Biochem., 85:678-688.
33. Walker, K.W., and Bradshaw, R.A. (1999) Yeast methionine aminopeptidase I. Alteration of substrate specificity by site-directed mutagenesis. J. Biol. Chem., 274(19):13403-13409.

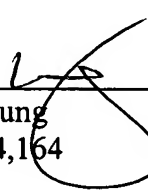
This Information Disclosure Statement is being submitted within three (3) months of the filing date or before any office action is issued. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).

By citing the above references, Applicants do not acquiesce or admit that any of these documents is "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned. Please apply any charges or credits to Deposit Account No. 06-1050.

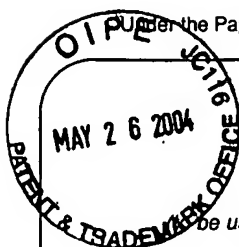
Respectfully submitted,

Date: May 26, 2004



Ping F. Hwung
Reg. No. 44,164

Fish & Richardson P.C.
500 Arguello Street, Suite 500
Redwood City, California 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071



TRANSMITTAL FORM

be used for all correspondence after initial filing)

Application Number	10/813,549
Filing Date	March 29, 2004
First Named Inventor	You-Di Liao
Group Art Unit	Unknown
Examiner Name	Unknown

Total Number of Pages in this Submission

12 (plus 32
references)

Attorney Docket Number

16743-004001

ENCLOSURES (check all that apply)

☒ Fee Transmittal Form

☒ Fee Attached

☐ Amendment / Response

☐ After Final

☒ Combined Declaration and Power of Attorney

☐ Extension of Time Request

☐ Express Abandonment Request

☒ Information Disclosure Statement

06/01/2004 JDALINAN 00000009 10813549

03 C:2051 ☐ Certified Copy of Priority Document(s) 65.00 OP
☐ Response to Missing Parts/
Incomplete Application

☐ Response to Missing
Parts under 37 CFR
1.52 or 1.53

☐ Assignment Papers
(for an Application)

☐ Drawings

☐ Licensing-related Papers

☐ Petition Routing Slip (PTO/SB/69)
and accompanying Petition

☐ Petition to Convert to a
Provisional Application

☐ Power of Attorney, Revocation
Change of Correspondence
Address

☐ Terminal Disclaimer

☐ Small Entity Statement

☐ Request for Refund

☐ After Allowance Communication
to Group

☐ Appeal Communication to Board
of Appeals and interferences

☐ Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Additional Enclosure(s)
(please identify below):

PTO-1449 form and 32 references
Return receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or
Individual name

Ping F. Hwung, Reg. No. 44,164

Signature

Date

[Signature]
May 26, 2004

06/01/2004 JDALINAN 00000009 10813549

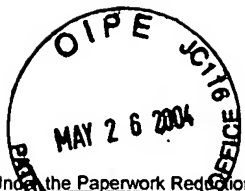
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FEE TRANSMITTAL

for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 477.00

Complete if Known

Application Number	10/813,549
Filing Date	March 29, 2004
First Named Inventor	You-Di Liao
Examiner Name	Unknown
Art Unit	Unknown
Attorney Docket No.	16743-004001

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number: 06-1050
Deposit Account Name: Fish & Richardson P.C.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	385
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$) 385

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid
Independent	Multiple Dependent	-20** =	-3** =			
23	1	3	3	9	43	27
						0

<u>Large Entity</u>		<u>Small Entity</u>		<u>Fee Description</u>
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	65
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	2053	130	Non-English specification	
1812	2,520	2812	2,520	For filing a request for ex parte reexamination	
1804	920*	2804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	2805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	2451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	2460	130	Petitions to the Commissioner	
1807	50	2807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	2806	180	Submission of Information Disclosure Stmt	
8021	40	28021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	2802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 65

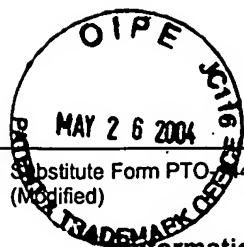
SUBMITTED BY

Name (Print/Type)	Ping F. Hwang	Registration No. (Attorney/Agent)	44,164	Telephone	(650) 839-5070
Signature		Date	May 26, 2004		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute Form PTO-1449 (Modified) Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16743-004001	Application No. 10/813,549
	Applicant You-Di Liao		
	Filing Date March 29, 2004	Group Art Unit Unknown	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,013,662	05/07/1991	Ben-Bassat, et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AL							
	AM							
	AN							
	AO							
	AP							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AQ	Abe, A., <i>et al.</i> (2000) Acetylation at the N-terminus of actin strengthens weak interaction between actin and myosin. <i>Biochem. Biophys. Res. Commun.</i> , 268:14-19.
	AR	Adachi, K., <i>et al.</i> (2000) Expression of functional soluble human α -globin chains of hemoglobin in bacteria. <i>Protein Expr. Purif.</i> , 20:37-44.
	AS	Belagaje, R.M., <i>et al.</i> (1997) Increased production of low molecular weight recombinant proteins in <i>Escherichia coli</i> . <i>Protein Sci.</i> , 6:1953-1962.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16743-004001	Application No. 10/813,549
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant You-Di Liao	
		Filing Date March 29, 2004	Group Art Unit Unknown

Other Documents (include Author, Title, Date, and Place of Publication)		
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	AT	Ben-Bassat, A., <i>et al.</i> (1987) Processing of the initiation methionine from proteins: properties of the <i>Escherichia coli</i> methionine aminopeptidase and its gene structure. J. Bacteriol., 169(2):751-757.
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	AW	Chang, S.Y., <i>et al.</i> (1989) Methionine aminopeptidase gene of <i>Escherichia coli</i> is essential for cell growth. J. Bacteriol., 171(7):4071-4072.
	AX	Chen, S., <i>et al.</i> (2002) The specificity <i>in vivo</i> of two distinct methionine aminopeptidases in <i>Saccharomyces cerevisiae</i> . Arch. Biochem. Biophys., 398(1):87-93.
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	AAA	Fischer, W.H., and Spiess, J. (1987) Identification of a mammalian glutaminyl cyclase converting glutaminyl into pyroglutamyl peptides. Proc. Natl. Acad. Sci. U.S.A., 84:3628-3632.
	ABB	Hirel, P.H., <i>et al.</i> (1989) Extent of N-terminal methionine excision from <i>Escherichia coli</i> proteins is governed by the side-chain length of the penultimate amino acid. Proc. Natl. Acad. Sci. U.S.A., 86:8247-8251.
	ACC	Huang, H.C., <i>et al.</i> (1998) The <i>Rana catesbeiana rcr</i> gene encoding a cytotoxic ribonuclease. Tissue distribution, cloning, purification, cytotoxicity, and active residues for RNase activity. J. Biol. Chem., 273(11):6395-6401.
	ADD	Hwang, D.D.W., <i>et al.</i> (1999) Co-expression of glutathione S-transferase with methionine aminopeptidase: a system of producing enriched N-terminal processed proteins in <i>Escherichia coli</i> . Biochem. J., 338(Pt 2):335-342.
	AEE	Ishitani, M., <i>et al.</i> (2000) SOS3 function in plant salt tolerance requires N-myristoylation and calcium binding. Plant Cell, 12:1667-1677.
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		Filing Date March 29, 2004	Group Art Unit Unknown

Other Documents (include Author, Title, Date, and Place of Publication)		
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	AGG	Li, X., and Chang, Y.H. (1995) Amino-terminal protein processing in <i>Saccharomyces cerevisiae</i> is an essential function that requires two distinct methionine aminopeptidases. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 92:12357-12361.
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	AII	Liao, Y.D., <i>et al.</i> (2000) Purification and cloning of cytotoxic ribonucleases from <i>Rana catesbeiana</i> (bullfrog). <i>Nucleic Acids Res.</i> , 28(21):4097-4104.
	AJJ	Liao, Y.D., <i>et al.</i> (2003) The structural integrity exerted by N-terminal pyroglutamate is crucial for the cytotoxicity of frog ribonuclease from <i>Rana pipiens</i> . <i>Nucleic Acids Res.</i> , 31(18):5247-5255.
	AKK	Lowther, W.T., <i>et al.</i> (1999) <i>Escherichia coli</i> methionine aminopeptidase: implications of crystallographic analyses of the native, mutant, and inhibited enzymes for the mechanism of catalysis. <i>Biochemistry</i> , 38:7678-7688.
	ALL	Lowther, W.T., and Matthews, B.W. (2000) Structure and function of the methionine aminopeptidases. <i>Biochim. Biophys. Acta.</i> , 1477:157-167.
	AMM	Moerschell, R.P., <i>et al.</i> (1990) The specificities of yeast methionine aminopeptidase and acetylation of amino-terminal methionine <i>in vivo</i> . Processing of altered iso-1-cytochromes <i>c</i> created by oligonucleotide transformation. <i>J. Biol. Chem.</i> , 265(32):19638-19643.
	ANN	Notomista, E., <i>et al.</i> (1999) Effective expression and purification of recombinant onconase, an antitumor protein. <i>FEBS Lett.</i> , 463:211-215.
	AOO	Prchal, J.T., <i>et al.</i> (1986) Hemoglobin Long Island is caused by a single mutation (adenine to cytosine) resulting in a failure to cleave amino-terminal methionine. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 83:24-27.
	APP	Roderick, S.L., and Matthews, B.W. (1993) Structure of the cobalt-dependent methionine aminopeptidase from <i>Escherichia coli</i> : a new type of proteolytic enzyme. <i>Biochemistry</i> , 32:3907-3912.
	AQQ	Shapiro, R., <i>et al.</i> (1988) Expression of Met-(-1) angiogenin in <i>Escherichia coli</i> : conversion to the authentic <Glu-1 protein. <i>Anal. Biochem.</i> , 175:450-461.
	ARR	Tahirov, T.H., <i>et al.</i> (1998) Crystal structure of methionine aminopeptidase from hyperthermophile, <i>Pyrococcus furiosus</i> . <i>J. Mol. Biol.</i> , 284:101-124.
	ASS	Tobias, J.W., <i>et al.</i> (1991) The N-end rule in bacteria. <i>Science</i> , 254:1374-1377.
	ATT	Varshavsky, A. (1996) The N-end rule: functions, mysteries, uses. <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 93:12142-12149.

Examiner Signature	Date Considered
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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant You-Di Liao	
		Filing Date March 29, 2004	Group Art Unit Unknown

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AUU	Vetro, J.A., and Chang, Y.H. (2002) Yeast methionine aminopeptidase type 1 is ribosome-associated and requires its N-terminal zinc finger domain for normal function <i>in vivo</i> . J. Cell. Biochem., 85:678-688.
	AVV	Walker, K.W., and Bradshaw, R.A. (1999) Yeast methionine aminopeptidase I. Alteration of substrate specificity by site-directed mutagenesis. J. Biol. Chem., 274(19):13403-13409.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	